Bruce Darwin Spector, Esq.
December 11, 2005

VERMONT HEALTH RESOURCE ALLOCATION PLAN
SECTION FOUR:
CERTIFICATE OF NEED STANDARDS

Standards for Demonstrating Consistency with the Health Resource Allocation Plan (18 V.S.A. §9437(1)):

THE GUIDING PRINCIPLE:
Applicants' proposals shall measurably, appropriately and reasonably foster implementation of the following values expressed in the Institute of Medicine's (IOM) Aims.[1]

Principle 1. Safety – The Vermont health care system will be made ***safe*** by identifying strategies and implementing mechanisms to avoid injuries to patients from the care that is intended to help them and to provider staff from the environment that is intended to support them.

Sub-principle 1 (A). Health care providers should accept accountability for and public oversight of their services to ensure that they are appropriate, safe, effective and financially responsible.

Sub-principle 1 (B). Vermont should implement strategies to support use of information technology to improve quality and ensure safety by providing tools to providers, patients and their families to reduce medical errors, avoid unnecessary duplication of tests and other services, and improve coordination of patients' care.

Principle 2. Effectiveness – The Vermont health care system will be ***effective*** by identifying strategies and implementing mechanisms to provide services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit.

Sub-principle 2 (A). Vermonters should have access to health care services that support timely prevention, treatment and management of disease, with a particular emphasis on cost-effective services that are evidence-based or based on best practices.

Sub-principle 2 (B). Health care providers should maintain and measurably improve the quality of health care services offered to Vermonters.

Sub-principle 2 (C). High quality healthcare requires the collection and analysis of comprehensive and uniform utilization, health outcomes, price and cost data that are made available in a timely way to all providers, payers and purchasers to evaluate quality and quality improvement.

---

[1] Adapted from the Institute of Medicine, *Crossing the Quality Chasm, A New Health System for the 21st Century,* 2003.

Sub-principle 2 (D). Best practices and benchmark measures, including population-based measures, should be utilized to assess and evaluate the efficiency and effectiveness of Vermont's health care system and individual services proposed in CON applications.

Sub-principle 2 (E). Vermont should apply multiple strategies that consider equity, market, Certificate of Need, and others to achieve rationale allocation of health care resources.

Sub-principle 2 (F). The Vermont health care system should collaborate with the education system and employers to provide a continuum of workforce development and professional education programs to ensure the quality and availability of all types of health care workers required to meet the health care needs of Vermonters.

Principle 3. Patient-centeredness – The Vermont health care system will be ***patient-centered*** by identifying strategies and implementing mechanisms for provision of care that is respectful of and responsive to individual patient preferences, needs, and values and for ensuring that patient values guide all clinical decisions.

Sub-principle 3 (A). Vermont should support access to appropriate care and promote the provision of information necessary to enable patients to make a choice among providers that is consistent with safety, effectiveness, and efficiency.

Sub-principle 3 (B). In addition to providers, patients must be directly involved in determining quality standards and measures of outcomes.

Sub-principle 3 (C). Individuals and families should be primarily responsible, to the best of their ability and resources, for the maintenance of their health. State health policy should encourage providers and payers to provide incentives, education, and tools to encourage and assist individuals in taking responsibility for appropriate management of their health throughout the lifespan.

Sub-principle 3 (D). Vermont should promote education to help individuals make personal behavior choices that protect and foster good health including self-management of chronic diseases.

Sub-principle 3 (E). Vermont should support incentives to help payers, purchasers, providers and public health entities implement informed health care decision-making tools to help consumers make informed decisions about health plans, providers, medical treatments and costs.

Sub-principle 3 (F). Vermonters have the right to have the confidentiality of their personal, identifiable, healthcare-related data--protected in all systems, public and private.

Principle 4. Timeliness – The Vermont health care system will provide ***timely care*** by identifying strategies and implementing mechanisms to promote appropriate waits and avoid harmful delays for both those who receive and those who give care.

Sub-principle 4 (A). Vermont should implement strategies to encourage use of information technology by providers, patients and their families to identify and implement timely and appropriate care for prevention of disease and management of chronic diseases.

Sub-principle 4 (B). Vermont providers and payers should facilitate timely access to distant or out-of-state services that cannot be provided safely and efficiently in local settings.

Principle 5. Efficiency – The Vermont health care system will be ***efficient*** by identifying strategies and implementing mechanisms to avoid waste, in particular waste of equipment, supplies, ideas, energy and money.

Sub-principle 5 (A). Vermont's health care system should include consumer and provider incentives that encourage cost-effective health service utilization and best care management practices.

Sub-principle 5 (B). Vermont's healthcare resources should be integrated to offer an appropriate range of services in appropriate settings based on defined needs, and include primary, secondary, and tertiary interventions for all physical and mental conditions.

Sub-principle 5 (C). Stakeholders in Vermont's health care system should collaborate on planning, developing and operating programs, facilities and services to promote a high quality and cost-effective system.

Sub-principle 5 (D). Vermont should implement strategies to encourage use of information technology to decrease the occurrence of redundant medical tests and treatments.

Sub-principle 5. (E). Vermont should implement strategies to encourage use of information technology to increase provider productivity and to control costs in a manner that also ensures safety and quality of care.

Principle 6. Equity – The Vermont health care system will be ***equitable*** by identifying strategies and implementing mechanisms to provide care that does not vary in quality because of personal characteristics that are not in the control of individuals such as gender, ethnicity, geographic location, and socioeconomic status.

Sub-principle 6 (A). All Vermonters should have access throughout the lifespan to appropriate and quality health services at costs that are affordable.

Sub-principle 6 (B). Vermont should ensure that resource allocation decisions are based on the principles of population-based need in order to achieve cost-effective

and high quality health facility operations. The decision making process should also include consideration of other factors including requirements for service-specific clinical skills and patient travel distance to facilities.

CON STANDARDS:

1. The project is needed to meet an identifiable, existing, or reasonably anticipated need and:

a. current resources are unable to meet the need,
b. the project will improve health outcomes,
c. utilization review procedures will be put in place to ensure appropriate utilization, and
d. in the absence of the proposed new service, patients would experience serious problems in terms of costs, availability, quality, or accessibility in obtaining care of the type proposed.

2. That the proposed health care project will facilitate implementation of the HRAP concerning the resources, needs and appropriate system of delivery of health care services.

3. That the impact of the project on payers, including uninsured persons, insurers, employers, self-insureds, and State, federal and local governmental providers of health care benefits is necessary and reasonable.

4. That the project will help meet the needs of medically underserved groups and the goals of universal access to health services.

5. That the applicant has taken appropriate and reasonable steps, both prior to and in conjunction with development of the proposed project, to discover and implement collaborative approaches, in conformance with State and Federal laws, to meeting the needs identified in the proposal, including collaborating with other similar providers, dissimilar providers and other entities in its service area, in-state region, State, and appropriate regions beyond Vermont.

6. That the proposal will foster implementation of the Vermont Blueprint for Health: Chronic Care Initiative,[2] including the following goals and values:

a. Goals:

[2] See generally the Vermont State Health Plan and the Vermont Blueprint for Health Strategic Plan

1. Vermonters with chronic conditions will be effective managers of their own health.
2. The proportion of individuals receiving care consistent with evidence-based standards will increase.
3. Vermonters will live in communities that support healthy lifestyles, and have the ability to prevent and manage chronic conditions.
4. A chronic care information system (registry functionality) will be available to providers, which will support chronic disease prevention, treatment and management for effective individual and population-based care.
5. Vermonters will be served by a health care system that invests in and rewards quality.

b. Values:
   1. Self-care: empower and prepare patients to manage their health and health care; emphasize the patient's central role in managing their health; use effective self-management support strategies; organize internal and community resources to provide ongoing self-management support to patients.
   2. Community: mobilize community resources to meet needs of patients.
   3. Health Care System: create a culture, organization and mechanisms that promote safe, high quality care; visibly support improvement at all levels of the organization; encourage open and systemic handling of errors and quality problems; provide incentives based on quality of care; develop agreements that facilitate care coordination within and across organizations.
   4. Clinical Information System: organize patient and population data to facilitate efficient and effective care.
   5. Decision Support: promote clinical care that is consistent with scientific evidence and patient preferences: embed evidence-based guidelines into daily clinical practice.
   6. Delivery System Design: assure the delivery of effective, efficient clinical care and self- management support; define roles and distribute tasks among team members; use planned interactions to support evidence-based care; provide clinical case management services for complex patients; ensure regular follow up by the care team; give care that patients understand and that fits with their cultural background.

7. If a project proposes to, or is likely to, expand geographic access to services, that:

a. the current travel-time exceeds reasonable access standards;
b. the cost to those who finance Vermont's health care system will not increase unreasonably;
c. improvements in clinical outcome or quality of care are demonstrated that outweigh or justify any added cost, and

d. increased costs can, and should be, reasonably absorbed, or funded, by the payers

8. If a project proposes to retain access to one or more services, that:

a. maintaining the current level of access for each service is consistent with meeting the provisions in the Health Resource Allocation Plan;
b. the cost to those who finance Vermont's health care system will not increase unreasonably;
c. improvements in clinical outcome or quality of care are demonstrated that outweigh or justify any added cost, and
d. increased costs can, and should be, reasonably absorbed, or funded, by the payers;

9. Generally, that high-technology services new to Vermont are introduced first at tertiary care hospitals serving significant numbers of Vermonters, and that the scientific evidence from peer-reviewed journals or controlled studies will permit definitive conclusions concerning the effectiveness, safety and efficiency of the technology.

a. That protocols for each technology modality will be or have been developed to screen out inappropriate and inefficient use of the modality.
b. That acquisition of major medical equipment or services is included in the applicant's long-range plan, operating budget and capital budget where appropriate, and is consistent with the statewide targets or budgets adopted by the Department of Banking, Insurance, Securities, and Health Care Administration.

10. That, with respect to straight replacement of major medical equipment, existing equipment is fully depreciated, or the cost of early replacement, including the cost of remaining depreciation on the existing equipment, is demonstrated to be less costly.

11. That, with respect to radiation therapy:

a. For any radiation therapy service established outside of a tertiary center, formal linkages will be or have been established for on-going utilization review and quality assessment in collaboration with a tertiary center.
b. Any proposal for a new linear accelerator unit demonstrates that the accelerator will perform an adequate number of treatments per year, by the second year of operation, based on analyses of state regional and national benchmarks, to achieve sufficient utilization to ensure the additional unit is needed and will perform safely, effectively, and efficiently.

12. That, with respect to dialysis for end-stage renal disease:

Kidney dialysis of non-acute patients will be provided only through academic medical centers or applicants providing a comparable quality and

continuity of care and serving a significant number of Vermonters, either directly or through a satellite service, for both in-home and in-hospital dialysis, or at other locations providing a comparable quality and continuity of care.

13. That, with respect to open-heart surgery and cardiac catheterization:

a. Open-heart surgery will be provided only at Fletcher Allen Health Care, Dartmouth-Hitchcock, and Albany Medical Centers, or other out-of-state facilities qualified and approved by their State authorities to do so.
b. Cardiac catheterization services will be provided in accordance with the most current recommendations found in the August 1998 Report of the Cardiac Catheterization Work Group to the Division of Health Care Administration prepared by the Vermont Program for Quality in Health Care, or from subsequent such groups.

14. That, with respect to magnetic resonance imaging (MRI):

a. Fixed MRI capacity will not be increased until current capacity is in excess of valid state, regional and national benchmarks for medically necessary exams per year and sufficient additional need is demonstrated, based on analyses of state, regional and national benchmarks, to demonstrate that another fixed unit will achieve sufficient utilization to ensure the additional unit is needed and will perform safely, effectively and efficiently, and that information on current use documents the effectiveness of internal programs to eliminate unnecessary exams.
b. Forecasting use of MRI service employs use rates that take into account MRI specific data on use by Vermonters, and that the forecasting method employed is based on best practice and incorporates conservative use assumptions.
c. The conversion of a mobile service to a site employing a fixed unit will be accomplished without any increase in the costs and charges for the service at the hospital, based on the most current volume of the mobile service.
d. Prior to approving additional capacity, information on current use is provided that documents the effectiveness of the internal program to eliminate unnecessary exams.

15. That, with respect to computed (CT) tomographic scanning:

a. Forecasting use of CT service employs use rates and market share forecasts that take into account actual CT data on use by Vermonters.
b. The conversion of a mobile service to a site employing a fixed unit will be accomplished without any increase in the costs and charges for the service at the hospital, based on the most current volume of the mobile service.

c. Prior to approving additional capacity, information on current use and best practice will be provided documenting the effectiveness of the internal program to eliminate unnecessary exams.

16. That, with respect to mental health and substance abuse services, the project will:

a. foster the State's focus on developing a coordinated system that encourages access to the appropriate and least restrictive level of care;
b. reflect the desirability of retaining the designated local provider network for the treatment of individuals with long-term and severe psychiatric needs;
c. meet or exceed appropriate access and quality standards, including the following:
    1. Short term psychiatric care (not necessarily in a dedicated unit) and psychiatric emergency care should be available to most Vermonters within the geographic areas served by the designated agency system for mental health, substance abuse and developmental services.
    2. Psychiatric services in dedicated units should be available to most Vermonters within the hospital service areas for the regional and tertiary hospitals.
    3. Services should meet the six IOM Aims, with particular focus on achieving patient-centered (and family-centered) and safe care.
    4. Services should address unmet need in Vermont for:
        i. mental health, psychiatric and substance abuse services, particularly for children and adolescents;
        ii. access to intensive outpatient programs;
        iii. access to partial hospitalization programs;
        iv. improved treatment for suicidal patients;
        v. improved education and support for primary care providers, and better integration of primary care and mental health;
        vi. improved care for people with co-occurring disorders;
        vii. access to opiate addiction treatment (methadone and buprenorphine).
        viii. availability of outpatient services in order to decrease the demand for more costly emergency and hospital-based care
        ix. sufficient mental health and substance abuse prevention, screening and aftercare services;
        x. access to residential care;
        xi. peer recovery services
        xii. suicide prevention programs,
        xiii. a full range of community-based treatment and support,
        xiv. affordable housing options,
        xv. substance abuse primary prevention efforts,
        xvi. safe and sober housing for people in recovery,
        xvii. increased peer-operated programs for mental health recovery.

xviii. diversion programs such as use of the 72-hour emergency hold programs and other initiatives in psychiatric units in the State's local general hospitals as effective tools in diverting admissions from the Vermont State Hospital or its successor facilities.

xix. adjustments to the available beds at VSH or its successors made in accordance with the capacity of community programs to provide effective services.

xx. maintaining current levels of local capacity and also supporting necessary increases in existing facilities.

xxi. additional beds in community hospitals, to be measured on a case-by-case basis.

xxii. capacity in therapeutic community residences to be kept at levels adequate to assure maintenance of the census at Vermont State Hospital and its successor institutions at appropriate levels.

xxiii. organizations providing mental-health services to have linkage agreements with other appropriate providers in the community to assure a coordinated system of care that allows access to the appropriate level of care.

17. A proposal to establish an Ambulatory Surgical Center shall not be approved unless the applicant demonstrates that:

a. the procedures performed in the facility will be limited to those procedures that are not anticipated to require an overnight stay and that can be performed safely in such a center;

b. in order to ensure safety for patients who experience complications requiring transfer to a general hospital, the facility must be located within appropriate travel time to one or more licensed general hospitals where there are three or more operating rooms;

c. the facility will provide services for post-operative complications and inquiries by ambulatory surgical center patients on a 24-hour basis;

d. Demonstrate how the applicant will provide access to all residents of each community within the identified service area(s) without regard to individuals' payer type, insurance status or ability to pay for needed services.

e. the proposed facility will make the following assurances that if the ASC is approved it will:

1. secure and maintain Medicare certification, when appropriate (accreditation by other organizations is encouraged);
2. comply with the access requirements of § 504 of the Rehabilitation Act and those of the Americans with Disabilities Act;
3. develop and maintain a transfer agreement with at least one nearby hospital, as well as a transport agreement with an EMS service for its emergency transport requirements;

4. ensure that all staff are well qualified, and that the clinical personnel are eligible for --- or have privileges for --- similar surgical procedures at a local hospital;
5. report utilization data in a form consistent with the data provided by hospitals to the Division of Health Care Administration for similar ambulatory surgery cases; and,
6. institute a quality review system, and cooperate with all public and private review organizations: and demonstrate that it will institute best practices protocols.

18. That, with respect to nursing home care:

a. the applicant provide a written recommendation from the Agency of Human Services regarding plans to increase, reduce, or reconfigure the supply of nursing home beds,
b. the applicant provide the Department with the nursing home bed need determinations by the Department of Aging and Independent Living, which determinations will be regarded as persuasive and will be presumed as the best evidence available,
c. the applicant demonstrate the need for additional capacity to meet nursing home level of care, including documenting the options for developing additional community-based services including Medicaid waiver services, residential alternatives, and adult day programs,
d. the applicant demonstrate, in order to serve the State's goals of reducing expenditures for nursing home services and enhancing funding for non-institutional services, that its proposal complies with the Agency of Human Services' (AHS) initiatives with individual institutions to reallocate resources in an orderly manner while reducing the supply of nursing home beds.

19. That the applicant demonstrate, in a proposal to add swing beds, that:

a. The applicant has adequately explained why it is appropriate for a long-term patient requiring custodial services to be served in a swing bed despite the fact hospitals cannot normally afford to replicate the services commonly delivered in a nursing home, or other long-term care facility if appropriate, at a reasonable cost;
b. The size and the staffing of the swing bed unit and the diagnoses of the patients being served will not negatively and unreasonably affect the costs of the service and the types of patients that may be served appropriately;
c. Any further increases in the swing bed supply will take into account:
    1. Potential effects on the State Medicaid budget.
    2. Continuity of care for patients.
    3. Additional costs incurred in caring for patients.
    4. Appropriate environment for patients requiring short-term but clinically intensive oversight and/or treatment

20. That, with respect to applications for new home health agencies:

a. the applicant demonstrates that the addition of such agencies is necessary and reasonable, particularly in light of the data collected by the Department to monitor access to services provided through the currently-certified home health agencies and evidence provided by the applicant, interested parties, competing applicants, amicus curiae and members of the public;
b. the applicant demonstrates the financial impacts of the proposed project relevant to the provision of home health care and the State's goal of attaining universal access to such care are necessary and reasonable; and
c. the applicant demonstrates how it will provide access to all residents of each community within the identified service area(s) without regard to individuals' payer type, insurance status or ability to pay for needed services.
d. The impact of proposed new services on continued access to the existing continuum of services within each service area should be considered. Adverse impact on the continued accessibility of the full continuum of services should be avoided.

21. That, in the case of construction projects, both new and renovation:

a. the costs and methods of the proposed construction, including the costs and methods of energy provision and the probable impact of the construction project on the cost of providing health services are necessary and reasonable;
b. the project is cost-effective in terms of energy conservation measures;
c. the impact of construction on the cost of new services is necessary and reasonable;
d. in the case of new construction, that it is the best alternative; and
e. the construction project will comply with the Guidelines for Construction and Equipment of Hospital and Medical Facilities as issued by the American Institute of Architects (AIA), Committee on Architecture for Health that the applicant will comply with the terms of Section 504 of the Rehabilitation Act of 1973, related to handicapped access, and that the applicant will comply with the standards for commercial construction, assuring nondiscrimination on the basis of disability

22. For hospitals subject to budget review, that the proposed health care project's impact on the hospital's established budget(s) and the unified health care budget is necessary and reasonable.

23. That, the following services, primarily found in hospitals, are considered appropriate services to be provided in the following categories of hospitals:

a. Critical Access, Community, Regional, or Tertiary Hospitals in Vermont:
    1. Low-risk maternity care (including nursery)

2. General inpatient medical/surgical care
3. General intensive care
4. Pediatric care (not necessarily in a dedicated unit)
5. Short-term psychiatric care (not necessarily in a dedicated unit)
6. Routine imaging service (x-ray, radiographic, fluoroscopic, ultrasound, mammography, basic nuclear medicine and CT scanning)
7. Therapies (physical, speech, occupational and nutritional) Emergency care, including stabilizing major trauma cases before transfer and including psychiatric emergencies
8. Ambulatory surgery
9. Psychiatric services in dedicated units
10. Magnetic resonance imaging
11. Medical rehabilitation services in dedicated units
12. Renal dialysis

b. Tertiary Hospitals in Vermont:
   1. Kidney transplantation
   2. Major trauma treatment (massive head and or chest trauma)
   3. Neonatal intensive care
   4. Open-heart surgery

c. Hospitals outside Vermont providing specialized services:
   1. Experimental procedures (unless 100% supported by grant funds)
   2. Major burn care
   3. Organ transplantation (other than kidney or kidney/pancreas)
   4. Specialty pediatric care (e.g., open-heart surgery)